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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/751,654	12/29/2000	Sergei G. Bavykin	0003-00797	8872

7590 11/19/2002

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/751,654	Applicant(s) BAVYKIN ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on *12 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4)☒ Interview Summary (PTO-413) Paper No(s). 16
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other

Supplemental Action

1. Upon reconsideration of request for consideration of Amendment crossed in the mail, the previous supplemental action mailed on August 7, 2002 is withdrawn herein.

2. Applicants' response to the office action and amendment (Paper No.14) filed on August 12, 2002 has been entered.

Response to Arguments

3. Applicant's response to the office action (Paper No.14) is fully considered and deemed persuasive.

4. The objection made in the previous office action with respect to color drawings is withdrawn herein in view of Applicants' submission of substitute black/white drawings (Paper No. 11).

5. The objection made in the previous office action with respect to Oath/Declaration is withdrawn herein in view of Applicant's submission of substitute Oath/Declaration (Paper No. 10).

6. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.10, and 14).

7. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments (Paper No. 14) with respect to claims 1,3,4,8, 11 and 13-14 are considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg (USPN. 6,218,531) in view of Chakrabarti et al. (Int. J. Radiat. Biol., Vol. 75 (8), pp. 1055-1065, 1999).

Ekenberg teaches a method for isolating genetic material wherein the method comprises (i) disrupting cells to liberate genetic material contained in the cells with guanidine isothiocyanate-containing buffer (see column 7, lines 26-40); (ii) contacting the genetic material to a column in a manner to cause the genetic material to become immobilized to the column (see column 7, lines 48-52); and eluting the genetic material from the silica column (see column 7, lines 53-65). Ekenberg also teaches more than one buffer system comprising a lysis buffer, dilution buffer, and elution buffer (see column 7, lines 26-42); the process takes less than 1 hour, and more preferably less than 20 minutes (see column 9, lines 14-23); lysis buffer contains guanidine thiocyanate (see column 17, lines 29-35) and elution buffer contains EDTA (see column 16, lines 48-65); pressure is applied to elute the genetic material from the column (see

column 20, lines 14-55); the process is maintained between 30- 100 ^{0}C (see column 18 lines 4-23). However Ekenberg did not teach radical mediated labeling of the genetic material.

Chakrabarti et al. teach a method for radical mediated labeling of genetic material wherein Chakrabarti et al. teach that the method comprises (i) contacting double-stranded nucleic acid molecules with radical generating complexes to produce aldehyde –reactive probes on the nucleic acid molecules (see page 1056, column 1, paragraph 2, column 2, paragraphs 2.1-2.3) and reacting the aldehyde moieties with amine containing chromophore ($FARP_{hc}$, 7-hydroxycoumarin-3-carboxylic acid(((((amino-oxymethyl) carbonyl) hydrazine) carbonylethyl) amide (page 1056, column 2, paragraph 2.3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of isolating genetic material from cells as taught by Ekenberg with the method of radical mediated labelling as taught by Chakrabarti et al. because Chakrabarti suggests that "the new method for the fluorescent labeling of probe (nucleic acid) sites containing aldehyde groups and their proximity can trap aldehyde sites generated by bleomycin (radical generating drug) on genomic, plasmid or oligonucleotide DNA and fluorescence quenching indicates the presence of closely spaced aldehyde sites " (see page 1064, column 1, paragraph 2 and column 2, paragraphs 1-2). An ordinary practitioner would have been motivated to combine the method of isolating genetic material as taught by Ekenberg with the method of radical mediated labeling as taught by Chakrabarti et al. by limiting the genetic material to a radical mediated labeling to increase the recovery or trapping of genetic material sites containing aldehyde groups, which are otherwise be lost unidentified, for the expected advantage of developing a combined method of isolating and labeling genetic material for the

benefit of trapping more DNA by minimizing the process steps.

Further, selection of specific temperature and buffer ratios represents routine optimization with regard to isolation of genetic material, which routine optimization parameters are explicitly recognized in Ekenberg and Chakrabarti et al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of specific temperature and ratios of buffer solutions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M. Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
November 7, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER